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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|------------------------|----------------------|---------------------|------------------|
| 10/797,996 | 03/11/2004 | Lixiao Wang | S63.2-7182-US02 | 6285 |
| 490 7590 07/16/2007 VIDAS, ARRETT & STEINKRAUS, P.A. SUITE 400, 6640 SHADY OAK ROAD | | | EXAMINER | |
| | | | DANIELS, MATTHEW J | |
| EDEN PRAIRI | EDEN PRAIRIE, MN 55344 | | ART UNIT | PAPER NUMBER |
| | • | • | 1732 | |
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| | | | MAIL DATE | DELIVERY MODE |
| | | | 07/16/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | | | |
|--|---|--|--|--|--|--|
| · | 10/797,996 | WANG ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Matthew J. Daniels | 1732 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on 01 M | Responsive to communication(s) filed on <u>01 May 2007</u> . | | | | | |
| , | · | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| 4) Claim(s) 14-26 is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) 14-17 and 19-22 is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6)⊠ Claim(s) <u>18 and 23-26</u> is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and/or | r election requirement. | • | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Examine | r. | | | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | • | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | |
| application from the International Bureau | | | | | | |
| * See the attached detailed Office action for a list | of the certified copies not receive | ea. | | | | |
| Attachment(s) | _ | | | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4) Interview Summary Paper No(s)/Mail Da | | | | | |
| 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date | 5) Notice of Informal F 6) Other: | | | | | |

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DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Claims 18 and 23-26 in the reply filed on 1 May 2007 is acknowledged. The traversal is on the ground(s) that the species are so closely related that they can be examined together. This is not found persuasive because (a) it does not address any of the bases for restriction, namely distinctness or independence and burden, and (b) it does not provide evidence that the species are not patentably distinct.

2. The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

3. Rejections set forth previously are withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. Claims 18 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crocker (USPN 5843116) in view of Gore (USPN 3953566). As to Claim 18, Crocker teaches a method of forming the balloon comprising the steps of:
- i) providing first (Fig. 3, item 36), second (Fig. 3, items 40 and 44) and third tubes (Fig. 3, item 38);

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ii) inserting the first tube into the second tube (Fig. 3, items 40 and 44);

- iii) inserting the second tube into the third tube (Fig. 3);
- iv) inserting the first, second and third tubes into a balloon mold (7:35-50);
- v) expanding the first, second and third tubes at a desired temperature so as to form a balloon (7:35-50, particularly 7:37-40).

Crocker appears to be silent to the second tube formed of a tube made of a material selected from the group consisting of fluoropolymers and high density polyethylene. However, Crocker clearly suggests cross-linked polyethylene (5:35-39), and it is the Examiner's position that crosslinking would produce a polyethylene having a "high density", as claimed.

However, in the alternative, Gore teaches a PTFE (a fluoropolymer) tubular product (14:17-20)) having a dense structure and extremely high strength which would have been suitable for use in Crocker's method as the expansion limiting bands (Crocker, 5:28-30). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to incorporate the method of Gore into that of Crocker because:

- a) Crocker provides a lamination process (7:8-62), and Gore suggests that the PTFE material is useful in laminated structures (1:39-40).
- b) The extremely high strength product of Gore (1:30) would be desirable to Crocker in order to provide the suggested structural integrity and limited expansion of the balloon (5:46-52).

As to Claim 23, Crocker teaches a method of forming a balloon comprising the steps of:

- i) providing first (Fig. 3, item 36), second (Fig. 3, Items 40 and 44) and third (Fig. 3, Item 38) tubes,
 - ii) inserting the first tube into the second tube (Fig. 3);

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- iii) inserting the second tube into the third tube (Fig. 3);
- iv) laminating the first tube and the second tube together (7:8-62);
- v) laminating the second tube and third tube together so as to form at least a three tube laminate (7:8-62).

Crocker is silent to the second tube formed of expanded PTFE. However, Gore teaches a PTFE (a fluoropolymer) tubular product (14:17-20)) having a dense structure and extremely high strength which would have been suitable for use in Crocker's method as the expansion limiting bands (Crocker, 5:28-30). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to incorporate the method of Gore into that of Crocker because:

a) Crocker provides a lamination process (7:8-62), and Gore suggests that the PTFE material is useful in laminated structures (1:39-40).

b) The extremely high strength product of Gore (1:30) would be desirable to Crocker in order to provide the suggested structural integrity and limited expansion of the balloon (5:46-52).

As to Claim 24, Crocker provides first and third tubes laminated together at least in part (7:40-50). As to Claim 25, in the invention of Crocker the temperature was predetermined (7:40-50). As to Claim 26, Crocker teaches that while items 36, 40, and 38 may be bonded together (7:8-11), it is possible to attach the components without adhesively bonding or securing the two balloons together or in a configuration where the expansion limiting bands are merely sandwiched (7:23-25, 7:50-65) between the balloons. In either embodiment, subsequent expansion of the balloon would cause delamination of the first and second tubes and the second and third tubes upon blowing the balloon either by expanding the adhesively bonded areas or separating the unbonded areas.

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Response to Arguments

5. Applicant's arguments filed 1 May 2007 have been fully considered but they are not persuasive. The arguments appear to be on the following grounds:

a) Applicants assert that cross-linked polyethylene is different from high density polyethylene. Cross-linked polyethylene is a polyethylene that has been subsequently modified by linking its

molecules in a manner which changes the material from a thermoplastic to a thermoset. High

density polyethylene is a thermoplastic material.

b) Crocker provides expansion limiting bands 40/44 which are made of nondistensible materials

such as nylon, polyamide, Kevlar, cross-linked polyethylene and others, which are inelastic.

Gore does not suggest inelastic or nondistensible materials as required by Crocker. Therefore,

there would be no motivation to make the combination.

6. These arguments are not persuasive for the following reasons:

a) Applicants' position rests on the use of a relative term which is not differentiated in the specification by any material characteristics. Therefore, it is submitted that the reference provides a "high density" polyethylene, or that a high density polyethylene is produced as a result of crosslinking, and that the rejection based thereon is valid. It is submitted that it is not implicit that high density polyethylene is thermoplastic (or remains a thermoplastic material), as asserted by Applicants' arguments. See, for example, USPN 3376238 to Gregorian, which teaches providing a commercially available polyethylene, and crosslinking, providing a

crosslinked high density polyethylene (7:15-25, also see Example 1). Therefore, the asserted

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thermoplastic nature of the high density polyethylene, which does not appear to be supported by the specification and is not commensurate with the scope of the claim, is not sufficient to distinguish the claimed invention.

Arguments of counsel cannot take the place of factually supported objective evidence. See, e.g., In re Huang, 100 F.3d 135, 139-40, 40 USPQ2d 1685, 1689 (Fed. Cir. 1996); In re De Blauwe, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984). In this case, where the Applicants' argument for patentability rests on the definition of a relative term and asserted implicit material characteristics, factual or objective evidence has not been presented. b) In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it is submitted that Gore holds a material in its stretched condition, heats the material, cools the material, and releases the material, wherein the expansion is retained with little or no coalescence or shrinking upon releasing the cooled article. See Gore, 1:50-57. This produces an increase in the strength (Gore, 2:12). The elasticity of the material of Gore appears to be removed by the stretching, such that there is no shrinking upon releasing of the article, producing an "amorphous-locked" material (4:55) of a surprising increase in strength (3:64). Thus, the material of Gore appears to be an inelastic or nondistensible material as suggested by

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Crocker. Crocker is nonlimiting in the suggestion of "generally" nondistensible materials which may be used (5:35-39), and provides only examples of materials which may be used.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J. Daniels whose telephone number is (571) 272-2450. The examiner can normally be reached on Monday - Friday, 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on (571) 272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MJD 7/5/07

/Christina Johnson/ Christina Johnson Supervisory Patent Examiner AU 1732